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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,092	01/08/2001	Michael J. Cima	10436-0009-999	5650

23557 7590 06/16/2003

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT PAPER NUMBER

1639

DATE MAILED: 06/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/756,092

Applicant(s)
Cima et al

Examiner
Maurie G. Baker, Ph.D.

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 4, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 170-179 is/are pending in the application.
- 4a) Of the above, claim(s) 174 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 170-173 and 175-179 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. The Response filed April 4, 2003 (Paper No. 16) is acknowledged. Claims 1-169 were cancelled and claims 170-179 were added. Therefore, claims 170-179 are currently pending.
2. The newly added claims read on the elected invention in part. Namely, claims 170-173, 175-177 and 178-179 (in part) read on the elected invention. Newly added claim 174 and claims dependent thereon do not read on the elected invention for the reasons set forth below.
3. Newly submitted claim 174 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 174 is drawn to a “method of identifying compounds that inhibit crystallization of a small molecule pharmaceutical”. The previously examined claims were drawn to a “method of screening a plurality of solid-forms of a compound-of-interest”. Thus, it is “solid-forms” that are screened or identified in the elected method. Claim 174 is not drawn to screening or identifying “solid-forms”, but is drawn to “identifying compounds that inhibit crystallization”. Thus claim 174 represents an invention that is independent or distinct from the invention originally examined.
4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 174 and claims 178-179 (in part) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. With respect to claims 170-173, 175-177 and 178-179 (in part), although these claims are deemed to read on the elected invention, it is unclear which claims read on the previously elected species as the claims have been substantively changed over previously examined claims 39-46, 48-56, 58 and 59. Thus a new election of species requirement is set forth below. Note that the previous election requirement is still in effect, in as much as it reads on the newly presented claims.

6. Note MPEP 811: 37 CFR 1.142(a), second sentence which states: “[i]f the distinctness and independence of the invention be clear, such requirement will be made before any action upon the merits; however, it may be made at any time before final action in the case at the discretion of the examiner.” This means the examiner should make a proper requirement as early as possible in the prosecution, in the first action if possible, otherwise, as soon as the need for a proper requirement develops. Before making a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required. The examiner’s position is that such a burden exists due to the widely varying nature of the species.

7. Also see MPEP 811.02: Since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904 C.D. 63, 108 O.G. 1588 (Comm’r Pat. 1904).

Election/Restriction

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

<u>Species 1</u> : method of identifying crystalline polymorphs	claims 170, 173 & 177-179 in part
<u>Species 2</u> : method of identifying (crystalline) salts	claims 171, 175 & 177-179 in part
<u>Species 3</u> : method of identifying co-crystals	claims 172, 176 & 177-179 in part

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are *no claims* generic to all species.

9. The species are distinct, each from the other, because their structures and/or physical forms are different. They would also differ in their reactivity and the starting materials from which they are made and, for the different methods, the elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden.

10. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the


application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
June 13, 2003



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER